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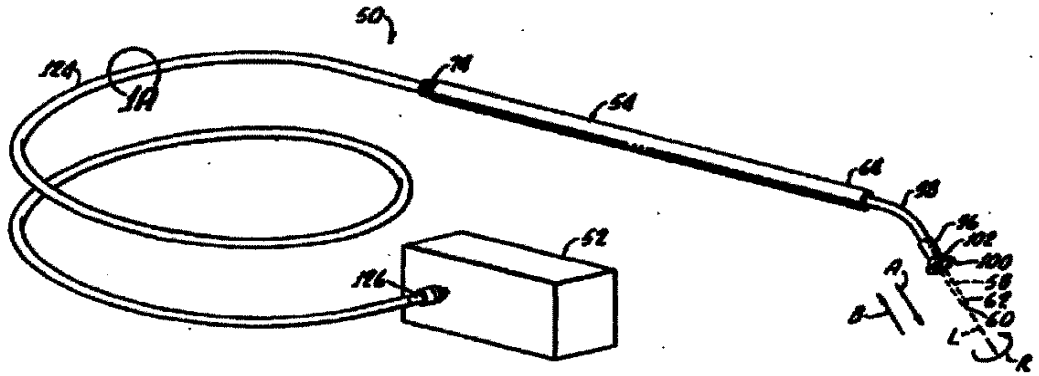

(57) Abstract

A tissue drill for reduced-trauma tissue ablation includes an optical fiber and a handpiece. The optical fiber has an inlet for receiving laser energy from a laser energy source and an outlet for emitting laser energy. The handpiece is adapted to receive the optical fiber in a controlled and movable relationship. In use, a distal end of the handpiece is placed against tissue to be ablated. The optical fiber is advanced beyond the distal end of the handpiece and into the tissue while emitting laser energy. The emitted laser energy ablates the tissue as the optical fiber advances. The optical fiber may then be retracted from the tissue, thereby resulting in a channel formed in the tissue. The optical fiber may also rotate while advancing into the tissue. In this regard, the outlet may be offset from a rotational axis of the optical fiber to reduce the level of laser energy transferred to surrounding tissue, thereby reducing trauma to the tissue. The tissue drill is particularly suited for performing transmyocardial revascularization (TMR) and similar procedures.

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Exhibit 1

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METHODS AND APPARATUS FOR ABLATING TISSUE

FIELD OF THE INVENTION

The present invention is directed to surgical methods and apparatus for ablating tissue. More particularly, the present invention is directed to surgical methods and apparatus for revascularizing tissue, for example, heart tissue, with laser energy in a consistent, precise, and programmable manner through the use of a laser tissue drill.

BACKGROUND OF THE INVENTION

Cardiomyopathy (*cardio* meaning "heart" and *myopathy* meaning "muscle disease") refers to a group of disorders that directly damage the muscle of the heart walls, or *myocardium*. In these disorders, all chambers of the heart are affected. The heart's function as a pump is disrupted, leading to an inadequate blood flow to organs and tissues of the body. Depending on the nature of the injury or abnormality in the heart muscle and the resulting structural changes in the heart chambers, one of three types of nonischemic (that is, not caused by heart attack) heart muscle disease may be present in a patient: *dilated congestive*, *hypertrophic*, or *restrictive*.

Dilated congestive cardiomyopathy damages the fibers of the heart muscle, weakening the walls of the heart's chambers. The chambers thereby lose some of their capacity to contract forcefully and pump blood through the circulatory system. To compensate for the muscle injury, the heart chambers enlarge or dilate which causes heart failure. Hypertrophic cardiomyopathy is characterized by a disorderly growth of heart muscle fibers causing the heart chambers to become thick walled and bulky. The thickening is generally most striking in the walls of the left ventricle, the chamber of the heart which pumps blood through the aorta to the vital organs and tissues of the body. The

distorted left ventricle contracts, but the supply of blood to the brain and other vital organs may be inadequate because blood is trapped within the heart during contractions. Restrictive cardiomyopathy causes abnormal cells, proteins, or scar tissue to infiltrate the muscle and structures of the heart, causing the chambers to become stiff and bulky. The heart may initially contract normally, but the rigid chambers restrict the return of blood to the heart.

Massive or multiple heart attacks may also lead to severe heart damage as a result of a disruption of blood supply to heart muscle. The damage can result in functional impairment and structural abnormalities similar to those found in the other types of cardiomyopathy. This type of heart disease, resulting from coronary artery disease, is called *ischemic cardiomyopathy* (*ischemic* meaning "lacking oxygen").

Severe heart injury caused by a major heart attacks or multiple smaller heart attacks may result in heart enlargement and thinning of the chamber walls, abnormalities which resemble those observed in dilated cardiomyopathy. Ischemic cardiomyopathy typically develops in patients with severe coronary artery disease, often complicated by other conditions such as diabetes and hypertension.

Although heart failure symptoms in ischemic cardiomyopathy are similar to those found in dilated cardiomyopathy, ischemic disease is more likely to be accompanied by symptoms of coronary artery disease, such as angina (which is chest pain resulting from reduced oxygen supply to the heart muscle). Diagnosis is typically based on a history of heart attacks and studies that demonstrate poor function in major portions of the left ventricle. The diagnosis can be confirmed by coronary angiography, which reveals areas of narrowing and blockage in the coronary blood vessels.

Patients with ischemic cardiomyopathy are treated with medications that relieve heart failure symptoms and improve blood flow through the diseased coronary arteries, such as nitroglycerin, some types of calcium channel

blockers, and angiotensin-converting enzyme (ACE) inhibitors. When symptoms of heart failure and coronary artery disease cannot be controlled with medications, coronary angioplasty or surgery may be considered. Angioplasty and coronary artery bypass grafting may help increase blood flow to the heart, which in turn enhances heart muscle function.

When heart failure symptoms are advanced and cannot be improved by drug therapy or surgery, patients may be referred for a heart transplant. Patients with ischemic cardiomyopathy account for approximately one half of all heart transplant recipients. With a limited supply of donor hearts and complications resulting from heart transplant (such as organ rejection), surgeons have been exploring alternative procedures for treating severe ischemic cardiomyopathy. One such procedure is *transmyocardial revascularization*, otherwise known more simply as "TMR."

TMR procedures revascularize, that is, form new vessels or channels, in the heart muscle or myocardium. The newly formed vessels penetrate through the entire heart wall, which includes the *epicardium* (the outer layer of the heart), the *endocardium* (the inner lining of the heart), and the myocardium or muscular wall therebetween. As ischemic cardiomyopathy more often than not afflicts the left ventricle, the new vessels are typically formed in the heart wall of this chamber of the heart. Accordingly, oxygenated blood from the lungs present in the left ventricle awaiting to be pumped through the aorta is able to flow directly into the newly formed vessels to nourish the heart muscle.

Pioneering methods for performing TMR involved the use of needles for physically puncturing holes in the heart wall. These methods resulted in only a temporary delivery of blood to the myocardium because the holes quickly healed at the endocardium, preventing oxygenated blood from entering the myocardium. One of the more recent and exciting methods of performing TMR is through the use of lasers. It has been observed that new vessels or channels formed in the heart wall by a laser tend to heal at the epicardium, which

prevents blood loss, and promote blood perfusion into the ischemic region of the myocardium.

Lasers have proven to be a widely useful and applicable tool in modern medical techniques, particularly in minimally invasive surgical procedures. Technically speaking, a laser (the word *laser* being an acronym for *l*ight *a*mplification by *s*timulated *e*mission of *r*adiation) utilizes the natural oscillations of atoms or molecules between energy levels for generating coherent electromagnetic radiation. A laser is able to produce high-intensity and high-energy light at a single frequency. The energy of laser light is measured in joules (J), or watt-seconds (W-s), and the power of a laser is measured in watts (W).

One of the conventional surgical apparatus for performing TMR consists of a laser and an optical fiber. A surgeon places the end of the optical fiber against the epicardium to ensure that all the laser light is focused at the desired point, and then the laser is fired. In order to form the new vessel completely through the heart wall and into the chamber, the surgeon needs to tactilely urge the optical fiber into and through the epicardium, the myocardium, and the endocardium. Because of the nature of ischemic cardiomyopathy, the thickness of the diseased myocardium is irregular and greater than normal. Accordingly, the surgeon needs to tactilely urge the optical fiber through the heart wall at each location. This procedure takes a certain amount of time to accomplish safely and involves a certain amount of guesswork on the part of the surgeon. This procedure is complicated by the beating of the heart. In addition, irregularly shaped holes may result if the surgeon does not urge the optical fiber into the tissue at a constant rate. For example, a cavity within the new hole may be formed if the surgeon slowed down or paused briefly at a particular location because more tissue at that location would be ablated by the increase in laser energy emitted over time. In addition, the increase in emitted laser energy may cause excessive trauma to the surrounding tissue at that location.

In many surgical applications, it may be desired to drill as large a hole as possible. For example, in treating an ischemic myocardium, holes with larger diameters have larger inner surface areas; accordingly, more blood is able to perfuse into the ischemic tissue. The difficulty in drilling relatively large holes (for example, about 1 mm) with laser ablation is that the area of the lasing plenum increases exponentially with an increase in the diameter of the hole (the *lasing plenum* being defined as the "bottom" of the hole subject to emitted laser energy). For example, the ratio between the areas of the lasing plenum of a hole with a 0.5-mm diameter and a hole with a 1-mm diameter is four. Conventional practice has been to increase the diameter of the optical fiber and, accordingly, the diameter of the laser beam to form larger holes. The power of the laser may also be increased. However, increasing the diameter of the laser beam results in an increase in the amount of energy emitted and, accordingly, an increase in the trauma of the surrounding tissue. In addition, the power of the laser energy can only be increased to a certain point until the capacity of the optical fiber is exceeded.

Accordingly, in view of the foregoing, it is an object of the present invention to provide methods and associated apparatus for forming holes or channels in tissue in a consistent and controlled manner.

It is another object of the present invention to provide surgical apparatus for forming holes or channels in tissue with a tissue drill using laser ablation.

It is a further object of the invention to provide surgical apparatus and method for forming holes in tissue in a substantially reduced traumatic manner.

It is yet another object of the present invention to provide methods and associated apparatus for performing transmyocardial revascularization.

SUMMARY OF THE INVENTION

These and other objects are achieved by the surgical apparatus and associated methods of the present invention which provides a tissue drill for

forming holes or channels in tissue by laser ablation in a controlled and consistent manner. In a broad aspect, the tissue drill for reduced-trauma tissue ablation includes an optical fiber and a handpiece. The optical fiber has an inlet for receiving laser energy from a laser energy source and an outlet for emitting laser energy. The handpiece is adapted to receive the optical fiber in a controlled and movable relationship. Exemplary handpieces can include flexible catheters, biocompatible tubular members, trocar sheaths, and the like. In use, a distal end of the handpiece is placed near or against tissue to be ablated. The optical fiber is advanced beyond the distal end of the handpiece and into the tissue while emitting laser energy. The emitted laser energy ablates the tissue as the optical fiber advances. The optical fiber may then be removed from the tissue, thereby resulting in a channel formed in the tissue. Although capable of performing all types of tissue drilling, the tissue drill of the present invention is particularly suitable for performing transmyocardial revascularization (TMR), which is the forming of channels in or through the wall of the heart.

The tissue drill of the present invention controls this tissue-ablating procedure. For example, the distance at which the optical fiber advances into the tissue may be predetermined and varied. Also, the emission of laser energy may be terminated as soon as the optical fiber has advanced the predetermined distance. In addition, the speed at which the optical fiber is advanced into the tissue may also be controlled and varied. This controllable and variable nature of the tissue drill enables a physician to program the tissue drill according to a particular procedure and a particular patient. It also provides a consistent procedure which allows multiple holes to be identically formed in tissue. By enabling a physician to control the drilling process in this manner, guesswork is substantially eliminated from the operation.

According to another aspect of the present invention, the handpiece of the tissue drill may be adapted to receive the optical fiber in a rotatable

relationship. In operation, while advancing into the tissue, the optical fiber may rotate while emitting laser energy. In this regard, the outlet may be eccentrically positioned with respect to the axis of rotation of the optical fiber. As such, the outlet rotates about the axis of rotation. This eccentric relationship results in laser energy being emitted and focused about the axis of rotation, which is essentially at a center of a hole being formed, and emitted at a lower level at a periphery of the rotating optical fiber, which is adjacent to tissue surrounding the hole being formed. Accordingly, a lower level of laser energy is incident on the surrounding tissue, thereby reducing trauma to the tissue.

The handpiece of the present invention may include a body portion and a coupling portion for receiving the optical fiber in controlled and axially movable relationship with respect to the body portion. The coupling portion may include a drive for moving the outlet of the optical fiber to a position beyond the distal end of the handpiece. The drive may also move the outlet to a position substantially at or near the distal end. Accordingly, the drive may reciprocate the outlet of the optical fiber between these advanced and retracted positions. The coupling portion may also be adapted to receive the optical fiber in a rotatable relationship. Alternatively, the handpiece may be a flexible tubular member such as a catheter with a drive and coupling portion positioned at a proximal end or on external equipment. In this regard, endovascular surgical procedures may be undertaken, such as performing transmyocardial revascularization from the inside of the left ventricle.

The optical fiber of the present invention may include an elongate portion and an outlet portion. A core of the elongate portion has an inlet for receiving laser energy, and a core of the outlet portion has an outlet for emitting laser energy. An axis of the core of the outlet portion may be oblique to an axis of the core of the elongate portion. This oblique relationship results in the eccentric position of the outlet with respect to the axis of rotation of the optical fiber discussed above. In addition, the outlet portion may have an end surface

from which the outlet emits laser energy. To provide the differing levels of laser energy emitted from the end surface as optical fiber rotates, the outlet has a diameter of at least approximately one half of a diameter of the end surface. Accordingly, a surface area of the outlet is at least one quarter of the surface area of the end surface. This relationship between diameters and surface areas results in an emission of laser energy focused about the axis of rotation and an intermittent emission of laser energy at the annular areas or the periphery of the end surface. Accordingly, tissue adjacent to the periphery of the end surface as the outlet portion advances is subject to a relatively low level of laser energy. This results in less trauma to the tissue which defines the inner surface of the newly formed channel. It has been observed that low-traumatized tissue has a likelihood to regenerate vascular tissue. Such revascularization or *angiogenesis* promotes the healing of the ischemic tissue.

Other aspects, features, and advantages of the present invention will become apparent to those persons having ordinary skill in the art to which the present invention pertains from the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an exemplary embodiment of a tissue drill of the present invention;

FIG. 1A is a cross-sectional view of an exemplary optical fiber of the invention taken along line 1A of FIG. 1;

FIG. 2A is a diagrammatic view of the exemplary tissue drill of the present invention, illustrating a handpiece receiving an optical fiber in a retracted position;

FIG. 2B is a diagrammatic view similar to that of FIG. 2A, illustrating the optical fiber in an advanced position;

FIG. 3A is a diagrammatic view of an exemplary handpiece of the tissue-drill of the present invention, illustrating the handpiece disassembled;

FIG. 3B is a diagrammatic view similar to that of FIG. 3A, illustrating the handpiece assembled;

FIG. 4 is a schematic view of an exemplary optical fiber of the present invention, particularly illustrating an eccentric configuration of an outlet portion of the optical fiber;

FIG. 5 is a schematic view of an end surface of the optical fiber illustrated in FIG. 4;

FIG. 6 is a schematic view of another exemplary optical fiber of the present invention;

FIG. 7 is a schematic view of an end surface of the optical fiber illustrated in FIG. 6;

FIG. 8 is a diagrammatic view of an exemplary end surface of an optical fiber of the present invention, particularly illustrating a relationship between emitted laser energy and position of the end surface;

FIG. 9 is a schematic view of an exemplary source of laser energy of the present invention;

FIG. 10A is a schematic view of an exemplary tissue drill of the present invention, particularly illustrating a step of a preferred tissue-drilling procedure implementing the tissue drill;

FIG. 10B is a view similar to that of FIG. 10A, illustrating a subsequent step in the tissue-drilling procedure;

FIG. 10C is a view similar to that of FIG. 10B, illustrating another subsequent step in the tissue-drilling procedure;

FIG. 10D is a view similar to that of FIG. 10C, illustrating yet another subsequent step in the tissue-drilling procedure;

FIG. 11 is a schematic view of tissue in which a hole has been drilled according to an exemplary method of the invention; and

FIG. 12 is a schematic view of tissue in which a hole has been drilled according to another exemplary method of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Referring to the drawings in more detail, in FIG. 1 an exemplary embodiment of a tissue drill 50 of the present invention is illustrated in conjunction with a source of laser energy 52. Exemplary tissue drill 50 forms holes or channels in tissue by laser ablation in a consistent, controllable, and programmable manner. Ablation is the process of fragmenting long molecules into short gaseous molecules. Much of the tissue in living organisms, including the human body, is made up mostly of water (e.g., about 75%) with organic material making up the remaining portion. The molecules of organic material consist of atoms of carbon, nitrogen, oxygen, and hydrogen that are attached together through covalent bonds. Ablation is the process of breaking these covalent bonds. Tissue drill 50 utilizes the ablation process to break molecules of tissue apart, thereby forming holes or channels in the tissue. The ablation process will be discuss in more detail below.

Exemplary tissue drill 50 includes a handpiece 54 for manipulation by a user and an optical fiber 56, which is shown in FIG. 1A, for transmitting laser energy from laser energy source 52. Optical fiber 56 has an outlet portion 58 for emitting laser energy. Outlet portion 58 functions substantially as a drill bit. In operation, outlet portion 58 is moved from a retracted position (which is shown in the solid line) to an advanced position (which is shown by the phantom line) while emitting laser energy. Arrow A represents outlet portion 58 moving to the advanced portion, and arrow L represents laser energy emitted from outlet portion 58. Tissue is ablated by laser energy as outlet portion 58 is advanced, thereby forming a hole or a channel in the tissue. Exemplary tissue drill 50 may also rotate outlet portion 58 while moving to the advanced position, which is represented by arrow R. After reaching the advanced position, outlet

portion 58 may be withdrawn to the retracted position, which is represented by arrow B. The advancing and retracting of outlet portion 58 is preferably along a central axis of optical fiber 56. Any rotation of outlet portion 58 is preferably about the central axis of optical fiber 56. The axial and rotational movement of outlet portion 58 will be discussed in more detail below.

Exemplary outlet portion 58 of optical fiber 56 has an end surface 60 with an outlet 62 from which laser energy is emitted. Outlet 62 is preferably offset from or eccentric to the central axis of outlet portion 58 so that as outlet portion 58 rotates, outlet 62 rotates about the central axis. Accordingly, laser energy emitted from outlet 62 as outlet portion 58 rotates is not focused at a single point but is rather distributed about the central axis. Alternatively speaking, the eccentric relationship of outlet 62 with respect to the central axis of outlet portion 58 preferably produces a gradient of laser energy as outlet portion 58 axially advances, with the highest level of laser energy at the central axis, which energy decreases toward a peripheral edge. The eccentricity of outlet portion 58 will also be discussed in more detail below.

Handpiece 54 may be implemented according to a variety of configurations. For example, handpiece 54 may be a flexible catheter utilized in endovascular procedures in conjunction with a camera. In this regard, outlet portion 58 may advance beyond a distal end of the catheter to vascularize tissue, such as on the inside the left ventricle of the heart. Alternatively, handpiece 54 may be formed as a trocar sheath and positioned intercostally (i.e., between the ribs) for tissue access. Handpiece 54 may also be formed in a gooseneck-like configuration with a plurality of articulated joints which may be bent to assume and retain a particular shape. Moreover, handpiece 54 may be a conduit with flexible cable sheathing. Accordingly, in a general sense, handpiece 54 provides a "user interface" for delivering outlet portion 58 to a target site, which may be accomplished either by direct physical manipulation by a surgeon or by programmed mechanical control.

An exemplary handpiece of the present invention is illustrated in FIGS. 2A and 2B. Exemplary handpiece 54 may include a body portion 64 and a coupling portion 66. Exemplary body portion 64 has a distal end 68. Exemplary coupling portion 66 is adapted or configured to receive optical fiber 56 in a controlled and axially movable relationship so that outlet portion 58 may be advanced beyond distal end 68 of body portion 64. In addition, coupling portion 66 may be adapted to receive optical fiber 56 in a rotatable relationship so that at least outlet portion 58 of optical fiber 56 may rotate. If handpiece 54 is configured as a catheter or similar flexible tubular member, the inner surface of the tubular member serves as a coupling portion by receiving optical fiber 56 in a controlled, axially movable, and/or rotatable relationship.

The retracted position of outlet portion 58 as shown in FIG. 2A may be defined as a position in which end surface 60 is positioned substantially at or near distal end 68 of body portion 64. Accordingly, end surface 60 may project slightly beyond distal end 68 or, alternatively, may be either proximal to or substantially aligned (or coplanar) with distal end 68. The advanced position of outlet portion 58 as shown in FIG. 2B may be defined as a position in which end surface 60 with outlet 62 projects a distance *d* beyond distal end 68 of body portion 64. As will be discussed in more detail below, distance *d* at which end surface 60 projects beyond distal end 68 is preferably predetermined, adjustable, and/or programmable.

With additional reference to FIGS. 3A and 3B, exemplary coupling portion 66 may include a drive which is comprised of a tubular member 70 and a collar 72. Tubular member 72 receives optical fiber 56 and may have a chuck 74 for retaining optical fiber 56 thereto. Tubular member 72 may also have annular threading 76 formed along a length thereof. Collar 72 is disposed within body portion 64 and has complementary inner threading 78. Exemplary tubular member 72 is slidably and rotatably receivable within body portion 64 with annular threading 76 engaging with inner threading 78 of collar 72, as

shown in FIG. 3B. Accordingly, rotation of tubular member 70 causes tubular member 70 to move axially. As optical fiber 56 is retained by chuck 74, optical fiber 56 with outlet portion 58 moves axially with tubular member 70. In an alternative embodiment of handpiece 54 such as a catheter, rather than disposing coupling portion 66 and a drive on handpiece 54, these elements may be provided at a proximal location, such as at laser apparatus 52. In this regard, catheter-configured handpiece 54 retains optical fiber 56 within a body portion which prevents buckling and which delivers outlet portion 58 to a target site but which is substantially free of coupling and drive apparatus.

Referencing FIG. 4, in addition to outlet portion 58, exemplary optical fiber 56 has an elongate portion 80. A core 82 and a cladding 84 define optical fiber 56 and extend along elongate portion 80 and outlet portion 58. Core 82 has an inlet 86 for receiving laser energy and outlet 62 (see also FIG. 1) for emitting laser energy. Core 82 and cladding 84 may be made of high-purity silica glass or sapphire, with core 82 having a higher index of refraction than that of cladding 84 so that modulated pulses of laser energy move along core 82 without penetrating cladding 84. Although optical fiber 56 may be configured according to any dimensions, for many applications a length l_e of elongate portion 80 may range from about 0.5 meter (m) to more than 2 m to provide a surgeon with sufficient maneuverability, and a length l_o of outlet portion 58 may range up to about 50 millimeters (mm) so that holes of different lengths may be formed in tissue. For applications other than medical, optical fiber 56 may be dimensioned accordingly to accomplish the particular application.

Core 82 of optical fiber 56 has an axis E along elongate portion 80 and an axis O at outlet 62. With additional reference to FIG. 5, core 82 along outlet portion 58 angles away from and is oblique to core 82 along elongate portion 80. At end surface 60, axis O of core 82 at outlet 62 is offset from or eccentric to axis E of core 82 of elongate portion 80 by a distance δ. Accordingly, laser energy emitted from outlet 62 is distributed about axis E as optical fiber 56

rotates about axis of rotation E. Further, the distribution of laser energy is across the entire surface area of end surface 60 as optical fiber 56 make one complete revolution. At end surface 60, outlet 62 may be configured so that axis O of core 82 is either oblique to axis E or, as shown, parallel to axis E.

An alternative exemplary embodiment of optical fiber 56 is illustrated in FIGS. 6 and 7. In addition to core 82 and cladding 84, exemplary optical fiber 56 may include auxiliary cladding 88 disposed about outlet portion 58. Similar to the embodiment shown in FIG. 4, to offset axis O of outlet 62 from axis of rotation E by distance δ, core 82 of outlet portion 58 is oblique to core 82 of elongate portion 80. Auxiliary cladding 88 compensates for the oblique relationship of core 82 (and cladding 84) of outlet portion 58 with respect to core 82 (and cladding 84) of elongate portion 80. Auxiliary cladding 88 accordingly provides a preferred cylindrical configuration of outlet portion 58 so that outlet portion 58 rotates about axis E as elongate portion 80 rotates about axis E. Further, in addition to axis O at outlet 62 being eccentric to axis E, axis O of core 82 may be oblique to axis E at outlet 62, rather than a parallel relationship as shown in FIG. 4.

As illustrated in FIGS. 6 and 7, end surface 60 (including outlet 62) is substantially perpendicular to axis E of exemplary optical fiber 56. To form the perpendicular relationship, core 82 and cladding 84 are ground or polished at an angle oblique to axis O, thereby removing portions of core 82 and cladding 84 shown by phantom line P. Accordingly, exemplary end surface 60 is substantially planar. Alternatively, end surface 60 may be convex, concave, or other configuration depending upon a particular implementation of outlet portion 58.

With particular reference to FIG. 7, end surface 60 of exemplary optical fiber 56 has a circumference C_{es} defined along an outer edge 90, and outlet 62 of core 82 has a circumference C_o defined along outer edge 92. Circumference C_{es} and circumference C_o are coextensive along an arc length α of outer edges 90

and 92. This relationship allows laser energy to be emitted from outlet 62 at outer edge 90 of end surface 60. As outlet portion 58 rotates, laser energy is emitted along circumference C_{es} of rotating end surface 60. Arc length α may range from a single tangent point to several seconds, minutes, or degrees as desired.

Diameter d_o of outlet 62 is preferably greater than about one half of diameter d_{es} of end surface 60. Accordingly, outlet 62 has a surface area which is at least one quarter of that of end surface 60. This relationship in surface area allows laser energy to be emitted from a substantial percentage of end surface 60. Further, laser energy is not emitted from the entire end surface 60 simultaneously but rather over the time it takes outlet portion 58 to make one revolution about axis E. An exemplary commercial embodiment of optical fiber 56 for use in transmyocardial revascularization entails a diameter d_{es} of end surface 60 (and outlet portion 58 of approximately 1 mm and a diameter d_o of outlet 62 of approximately 0.6 mm. Generally speaking, the dimensions of outlet portion 58 are determined by the type of procedure being performed and the desired size of the hole, with diameter d_o of outlet 62 being at least one half of diameter d_{es} of end surface 60. For example, if a hole with a 1.5-mm diameter is desired, then diameter d_{es} of end surface 60 (and outlet portion 58) should be about 1.5 mm; diameter d_o of outlet 62 may accordingly range from about 0.75 mm to slightly less than 1.5 mm, but is preferably about 0.8 mm. For many medical applications, it is contemplated that diameter d_{es} of end surface 60 may range from about 0.2 mm to more than 2.5 mm, with diameter d_o of outlet 62 ranging from less than about 0.1 mm to about 2 mm or more. For specific medical applications such as transmyocardial revascularization (which will be discussed below), diameter d_{es} of end surface 60 may range from about 0.6 mm to about 2 mm, with diameter d_o of outlet 62 ranging from about 0.3 mm to about 1 mm.

With additional reference to FIG. 8, end surface 60 is schematically illustrated during rotation, with outlet 62 shown at progressive instances in time t_1, t_2, t_3, and t_4 while rotating about axis E. Because of the relationship between the surface areas of end surface 60 and outlet 62, laser energy is continuously emitted from an area 94 of end surface 60. In other words, area 94 represents an intersection of the positions of outlet 62 at every instance of time while rotating about axis E. Laser energy is accordingly emitted at intervals at other areas of end surface 60 depending upon the position of outlet 62 at a particular instance in time.

The relationship between laser energy emitted from exemplary end surface 60 per revolution of outlet 62 about axis E with respect to distance from axis E is illustrated graphically in FIG. 8. Emitted laser energy per revolution of outlet portion 58 decreases from a constant level at area 94 to a lower level at outer edge 90 of end surface 60. In the graph, outer edge 90 is a distance from axis E substantially equal to radius r_{es} of end surface 60. Depending upon a particular configuration of exemplary end surface 60 and outlet 62, the decrease in laser energy or flux with respect to position may be a linear function as shown or a nonlinear function. Also, the relative level of energy per revolution at area 94 and at radius r_{es} is illustrative only, as the level of energy at the periphery of end surface 60 may vary according to the particular surgical procedure. For example, the energy flux at radius r_{es} may be at a relatively low level when compared to the constant level at area 94.

In accordance with this energy distribution per revolution of the present invention, while ablating tissue to form a hole, the transference of laser energy to peripheral or surrounding tissue is less than at a center of the hole being formed. This distribution of laser energy may limit trauma to tissue in which holes or channels are formed. More specifically, as outlet portion 58 moves through tissue while rotating and emitting laser energy, outer edge 90 of end surface 60 is adjacent to and contacts the surrounding tissue which defines the

hole being formed. As the level of emitted laser energy at outer edge 90 is lower than that centered about axis E (which essentially defines the center of the hole being formed), damage to the surrounding tissue is reduced, resulting in less trauma to the tissue. It is believed that tissue with a relatively low level of trauma has a likelihood to experience angiogenesis, or the formation of new blood vessels in the tissue. This reduced-trauma feature of the present invention will be discussed in more detail below.

An exemplary process to form an eccentric outlet portion 58 as described above involves placing the distal end of optical fiber 56 within a Teflon® tube at an angle, with cladding 84 contacting the inner surface of the tube at one point. The tube may then be filled with epoxy which surrounds the distal end of optical fiber 56 except at the point at which cladding 84 contacts the tube. After the epoxy has cured and hardened, the tube is removed, and the distal surface of the epoxy and optical fiber 56 is polished to define end surface 60 at the point where cladding 84 defines an annular edge of outlet portion 58. End surface 60 may also be formed with a lens to control the emission of the laser energy in a particular manner. An inner diameter of the tube for forming outlet portion 58 essentially determines the diameter of outlet portion 58 (i.e., diameter d_e, of end surface 60). According to this process, optical fibers 56 having outlet portions 58 of different diameters may be formed, enabling surgeons to form holes with a variety of diameters. In addition, a plurality of outlet portions 58 each having a different diameter may be formed, each of which being able to be coupled to an optical fiber, so that a set of interchangeable "drill bits" is at a surgeons disposal during a particular procedure. Optical fiber 56 may be reusable or disposable, as may outlet portion 58 and handpiece 54.

With further reference to FIGS. 1 and 3A, exemplary of handpiece 54 may include a head portion 96 connectable to a distal end of body portion 64 by a neck 98. Distal end 68 of body portion 64 is accordingly defined by a tissue

end 100 of head portion 96. Exemplary head portion 96 may be conical so that tissue end 100 has a larger diameter than body portion 64. Tissue end 100 provides a working surface or a tissue-engaging surface for positioning handpiece 54 over and against a surgical site in which a channel is to be drilled into tissue. Exemplary head portion 96 may also have an aperture 102 formed therein. Aperture 102 may function as a window for viewing a surgical site when tissue end 100 is placed against tissue. Aperture 102 may also function as a vent for exhausting gases which may be generated by laser energy ablating tissue. As shown in FIG. 1, exemplary neck 98 may be angular to enhance the positioning of head portion 96 against tissue. In this regard, neck 98 may be configured as a gooseneck with articulable joints for assuming and retaining a desired shape. Exemplary head portion 96 and neck 98 are preferably tubular, thereby providing an inner continuum with body portion 64 in which optical fiber 56 is receivable.

In particular procedures, it may be preferable to know where a hole has been drilled in tissue. However, the nature of the tissue or the size of the hole may render it difficult for the surgeon to determine where a hole has already been formed. Accordingly, the newly formed hole drilled in tissue may be marked. In this regard, head portion 96 may include apparatus for marking where a hole has been drilled in tissue. For example, tissue end 100 may have an inking device which dispenses biocompatible ink or dye on the tissue where a hole has been formed. The ink may be applied to the tissue through direct contact with tissue end 100 or, for example, by spraying. Exemplary handpiece 54 may have a reservoir for storing and dispensing a colored liquid or a particulate solid to the tissue. Fluorescent material may be used to enhance visualization. Other indicia may be applied to the tissue by handpiece 54 or head portion 96 at the target site; for example, alphanumeric indicia may indicate the parameters of the laser energy emitted from outlet 62 to form a particular hole.

With further reference to FIGS. 2A to 3B, exemplary coupling portion 66 may include a spring 104 receivable against a seat 106 formed on a distal end of collar 72, and a stop 108 disposed on a distal portion of tubular member 70. Spring 104 and stop 108 define a mechanism for controlling a position of tubular member 70 within body portion 64, and may be configured to facilitate the advancement and retraction of tubular member 70.

Exemplary source of laser energy 52 is illustrated in FIG. 9. Laser energy source 52 includes a laser 110 for generating laser energy L. Exemplary laser energy source 52 may include a drive assembly 112 for operatively associating with handpiece 54 and optical fiber 56, and may also include a control unit 114 with a user interface 116. Exemplary drive assembly 112 may include a coupler 118 for connecting with optical fiber 56, optics 120 for modifying laser energy L as desired, and a drive/motor 122. Exemplary coupler 118 is associated with optics 120 for transferring laser energy L from laser 110 to the inlet of optical fiber 56. Exemplary coupler 118 is also associated with drive/motor 120 for rotating optical fiber 56.

As discussed above in reference to FIGS. 2A and 2B, exemplary coupling portion 66 of handpiece 54 translates rotational movement of optical fiber 56 to axial movement to advance and to retract outlet portion 58. Exemplary drive assembly 112 preferably rotates optical fiber 56. For example, coupler 118 may secure and retain a proximal end of optical fiber 56, with motor/drive 122 rotating coupler 118 which also rotates optical fiber 56. Drive assembly 112 may rotate optical fiber 56 in a first direction, for example, as shown by arrow R_1 in FIG. 2A, to cause optical fiber 56 to advance axially as shown by arrow A. When outlet portion 58 reaches the desired advanced position, drive assembly 112 may then rotate optical fiber 56 in an opposite second direction, as shown by arrow R_2 is FIG. 2B, to cause optical fiber 56 to retract axially as shown by arrow B. Exemplary drive assembly 112 may oscillate optical fiber 56 (that is, rotate optical fiber 56 clockwise and

counterclockwise as shown by arrows R_1 and R_2) so that outlet portion 58 reciprocates between the retracted position and the advance position.

Exemplary laser energy source 52 preferably controls when laser energy L is emitted from outlet portion 58 of optical fiber 56. For example, control unit 114 in association with laser 110 and drive assembly 112 may limit the emission of laser energy L to only when outlet portion 58 moves to the advance position. Laser energy L may then be terminated during the retraction of outlet portion 58. Alternatively, if drive assembly 112 is reciprocating outlet portion 58, laser energy L may be transmitted only during the advancing stroke of outlet portion 58; the emission of laser energy L may then be terminated at the end of the advancing stroke. The termination of laser energy L upon reaching the advanced position is preferably automatic and controlled by laser energy source 52. Alternatively, laser energy L may be terminated by a device such as a pressure sensor which determines when the distal end of outlet portion 58 advanced completely through a section of tissue, e.g., the wall of the heart. This control of laser energy L is preferable during particular applications of tissue drill 50, which will be discussed in more detail below.

With further reference to FIG. 1A, optical fiber 56 is preferably received within a housing 124. In addition to protecting optical fiber 56, exemplary housing 124 constrains any torsional flexing or bending of optical fiber 56 which may result from the rotation by drive assembly 112. Exemplary optical fiber 56 may include a complementary coupler 126 for connecting with coupler 118 of laser energy source 52. Complementary coupler 126 preferably provides a releasable association with coupler 118 so that other optical fibers in accordance with the present invention may be connected to laser energy source 52. Exemplary housing 124 preferably extends between coupler 126 and chuck 74 of coupling portion 66 to provide integral protection of optical fiber 56 between laser energy source 52 and handpiece 54.

Exemplary laser energy source **52** may control a number of parameters of tissue drill **50**, including distance *d* at which outlet portion **56** advances, a speed at which outlet portion **56** advances, and a level at which laser energy is emitted from outlet **62**. Control unit **114** in association with user interface **116** preferably controls, programs, monitors, and/or adjusts each of these parameters depending upon a particular tissue-drilling application. For example, one the many applications of tissue drill **50** is for drilling holes or channels into or through heart walls. This procedure is known as *transmyocardial revascularization* or, more simply, as TMR. FIGS. **10A** through **10D** schematically illustrate an exemplary TMR procedure implementing tissue drill **50** of the present invention.

A heart wall **130** is illustrated in FIG. **10A** and includes myocardium, or heart muscle, **132** positioned between an outer serous layer or epicardium **134** and an inner membrane or endocardium **136**. It has been found to be medically beneficial to revascularize the myocardium of patients suffering from severe ischemic cardiomyopathy. The revascularization of the myocardium **132** involves forming new channels in the tissue. By implementing exemplary tissue drill **50** of the present invention, new channel may be formed in the myocardium in a controlled, consistent, and programmable manner.

Prior to a TMR procedure, the level at which laser **110** is to generate laser energy L and the frequency at which laser energy L is to be pulsed may be determined. In addition, distance *d* at which outlet portion **58** is to advance beyond distal end **68** and the speed at which outlet portion **58** is to rotate may be determined. These parameters may be stored in control unit **114** and varied or programmed via user interface **116**.

During the TMR procedure, access to the patient's chest cavity is provided, preferably by a minimally invasive procedure such as an intercostal incision using trocar sheaths. Access to the patient's heart is then provided, for example, by incising the pericardium. With outlet portion **58** in the retracted

position, a surgeon may then maneuver head portion 96 of handpiece 54 into the chest cavity and position tissue surface 100 against the epicardium 134, as shown in FIG. 10A. As discussed above, outlet portion 58 may project slightly beyond distal end 68 (that is, tissue end 100) when in the retracted position to provide the surgeon with a tactile feel of the position of end surface 60 on the epicardium 134.

When in the desired position on the epicardium 134, tissue drill 50 may be activated. This activation may be accomplished manually by an assistant via user interface 116 or by the surgeon with a foot or a hand trigger. Alternatively, activation of tissue drill 50 may be synchronized with the electrical activity of the heart through the use of an electrocardiogram (EKG) machine. Activation of tissue drill 50 causes laser energy source 52 to generate and transmit laser energy to optical fiber 56. Activation also causes optical fiber 56 to rotate and advance outlet portion 58 through the epicardium 134 and into the myocardium 132 of the heart wall 130, as shown in FIG. 10B.

Outlet portion 58 continues to advance through the myocardium 132 and through the endocardium 136. When end surface 60 of outlet portion 58 has advanced through the endocardium 136 and is positioned within the left ventricle of the patient's heart as shown in FIG. 10C, the emission of laser energy is preferably terminated, and the outlet portion 58 is retracted. A new channel 138 through the heart wall 130 results from this procedure as shown in FIG. 10D. Oxygenated blood from the left ventricle may enter the new channel 138 through the endocardium 136 and perfuse the tissue of the myocardium 132 surrounding the new channel 138. When handpiece 54 is configured as a catheter, outlet portion 58 advances through the endocardium 136 and then into the myocardium 132. Because outlet portion 58 may be programmed to advance a predetermined distance, outlet portion 58 may either continue to advance completely through the epicardium 134 or begin to retract the

predetermined distance within the myocardium **132**, thereby forming a hole in the heart wall **130** rather than a channel through the heart wall **130**.

As mentioned above, reduced trauma to the myocardium **134** surrounding the new channel **138** results from the eccentric relationship between outlet **62** and rotational axis E. This reduced trauma may enable the surrounding tissue to regenerate vascular tissue from the new channel **138** and into the myocardium **134** or to experience angiogenesis. In addition to the eccentricity of outlet portion **58**, the level of trauma inflicted on the surrounding tissue is mediated by the level of laser energy emitted from outlet **62**, which will now be discussed.

With reference to FIG. **9**, the energy level at which laser energy L is generated and transmitted to optical fiber **56** may be varied, programmed, and controlled according to each tissue-drilling application. For example, tissue drill **50** may be configured for drilling holes in all types of animal tissue and plant tissue, as well as other substances. The parameters which define the characteristics of laser ablation include frequency, energy per channel, pulse width, and pulse rate. As mentioned earlier, ablation is a process of breaking bonds between atoms in molecules by adding energy to the molecules. One preferred level of the laser energy L for TMR applications is to limit the energy per pulse to less than about 100 milliJoules per square millimeter of area (mJ/mm^2). More preferably, an energy per pulse of about 30 mJ/mm^2 has been found to ablate cardiac tissue at a substantially reduced level of trauma. The energy per pulse of laser **110** may be varied according to specific tissue-drilling procedures.

With further reference to FIGS. **3A** and **3B**, the drive may be configured to control the rate at which outlet portion **58** advances and retracts. The rate of advancement is controlled by the speed at which optical fiber **56** rotates and the pitch of the complementary threading of collar **72** and tubular member **78**. For smooth and continuous operation, it has been determined that optical fiber **56** and,

accordingly, outlet portion 58 should rotate at a speed under about 5,000 revolutions per minute (RPM). For TMR applications of tissue drill 50, a rotational speed ranging from about 1,000 RPM to about 2,000 RPM is preferred. In this regard, a specific TMR configuration of tissue drill 50 may be as follows. Optical fiber 56 may rotate at about 1,340 RPM. The pitch of threading 76 and 78 may be configured so that outlet portion 58 advances at a rate of about 15.5 millimeters per second (mm/s). With a rotational speed of 1,340 RPM, it takes about 46 milliseconds (ms) for outlet portion 58 to complete one rotation. For TMR applications, laser 110 may emit pulses of laser energy L of about 20 nanoseconds (ns) in duration, with each pulse being separated by about 4 ms. The pulse rate may be about 10 pulses per revolution (or at about every 36° of rotation) or about 240 pulses per second.

Rather than advancing and retracting outlet portion 58 at a constant rate as described above, tissue drill 50 may be configured such that outlet portion 58 moves at varying rates of speed between the retracted and advanced positions. The slower outlet portion 58 advances (or retracts) while emitting laser energy L, the more tissue that becomes ablated because the tissue is subject to more laser energy over time. Accordingly, a hole may be formed with a diameter greater than diameter d_{es} of end surface 60 (and outlet portion 58) by advancing outlet portion 58 at a speed which allows laser energy L to ablate a greater amount of tissue. Alternatively, the power of laser energy L may also be varied during the advancement of outlet portion 58 so that the tissue is subjected to more or less laser energy L. Generally speaking, a surgeon may program tissue drill 50 to ablate tissue at varying levels of energy per unit time to form holes of varying desired diameters or configurations. The energy per unit time may be adjusted by varying either the speed at which outlet portion 58 advances (which varies the time the tissue is subject to laser energy) or the level of laser energy, or both.

In order to form the substantially cylindrical hole 138 shown in FIG. 10D, tissue drill 50 advanced outlet portion 58 at a substantially constant speed, and

laser energy source 52 emitted laser energy at a substantially constant level. However, if a conical-shaped hole 140 as shown in FIG. 11 is desired, with the apex of the hole 140 positioned at the epicardium 134 and the base of the hole 140 positioned at the endocardium 136, then tissue drill 50 may be configured to advance outlet portion 58 at a decreasing rate (i.e., moving at a slower and slower speed) while advancing through the heart wall 130 from the epicardium 134 to the endocardium 136. Accordingly, a greater amount of tissue is ablated as outlet portion 58 advances at a slower speed. The resulting hole 140 has a diameter substantially equal to diameter d_{es} of outlet portion 58 at the epicardium 134 and a diameter larger than diameter d_{es} at the endocardium 136. By forming the hole 140 with a relatively large diameter at the endocardium 136 improves the patency of the hole and, therefore, the perfusion of the blood into the myocardium 132. In addition, by forming a hole with as small a diameter as possible at the epicardium 134 minimizes bleeding and trauma.

With reference to FIG. 12, another noncylindrically shaped hole 142 is shown. Rather than forming hole 142 by advancing outlet portion 58 from the epicardium 134 to the endocardium 136 as shown in FIG. 11, hole 142 is formed endovascularly, with outlet portion 58 advancing from the endocardium 136 and into the myocardium 132 a predetermined distance *d*. As mentioned above, to form holes endovascularly, handpiece 54 may be configured as a catheter, with access to the left ventricle of the heart provided through, for example, a femoral artery and the aorta. To form hole 142 with a diameter greater than diameter d_{es} of end surface 60 at the endocardium 136, tissue drill 50 is configured to advance outlet portion 58 relatively slowly at or near the epicardium 136 and then to increase the speed. This results in more tissue being ablated at or near the endocardium 136 than at the "bottom" of hole 142 within the myocardium 132. Laser energy may also be emitted while outlet portion 58 retracts to ablate more tissue toward the endocardium 136. The speed of advancement may be varied by varying either the revolutions per second at which outlet portion 58 rotates or the

pitch of threading 76 and/or 78, or both. As mentioned above, rather than varying the speed at which outlet portion 58 advances, the level of emitted laser energy L may be varied. In this regard, to form hole 142, tissue drill 50 may be configured to emit laser energy L at a relatively high level when outlet portion 58 begins to advance, and then to decrease the level as outlet portion 58 advances distance *d*.

Alternatively, rather than adjusting the speed or the energy level, outlet portion 58 may reciprocate a multiple of times either at increasing depths or at decreasing depths. For example, referencing FIG. 12, if the desired depth of the hole to be formed is distance *d* (that is, the distance end surface 60 advances beyond the distal end of handpiece 54), then tissue drill 50 may be configured to advance outlet portion 58 a distance *d* on a first stroke and then to advance outlet portion 58 a distance which incrementally decreases for each subsequent stroke for a predetermined number of strokes. Accordingly, even though the speed at which outlet portion 58 advances and the level at which laser energy L is emitted, hole 142 may be formed with a relatively large diameter at the endocardium 136 and tapered toward the epicardium 134 because tissue toward the endocardium 134 is subject to repeated laser energy with the multiple strokes of outlet portion 58. Therefore, a greater portion of this tissue is ablated because of the increased level of energy received per unit time. Alternatively, rather than decreasing the distance of the stroke, the distance of each multiple stroke may be incrementally increased to form hole 140 of FIG. 11. In addition, if it is desired to form a hole with a relatively large-diameter inner chamber, then tissue drill 50 may pause outlet portion 58 at a predetermined distance for a predetermined amount of time to concentrate laser energy at one location to ablate a relatively large portion of tissue at that location.

Those skilled in the art will understand that the embodiments of the present invention described above exemplify the present invention and do not limit the scope of the invention to these specifically illustrated and described embodiments. The scope of the invention is determined by the terms of the

appended claims and their legal equivalents, rather than by the described examples. In addition, the exemplary embodiments provide a foundation from which numerous alternatives and modifications may be made, which alternatives and modifications are also within the scope of the present invention as defined in the appended claims.

CLAIMS

What is claimed is:

1. A tissue drill for reduced-trauma tissue ablation, said tissue comprising:

an optical fiber having a laser inlet end and a laser outlet end;

a handpiece adapted to receive said optical fiber in controlled, reciprocating relationship thereto; and

a laser coupled to said laser inlet end in light-conducting relationship.

2. A tissue drill as claimed in claim 1 wherein:

said handpiece has a distal end; and

said laser outlet end of said optical fiber reciprocates from said distal end.

3. A tissue drill as claimed in claim 2 wherein said laser outlet end reciprocates from said distal end between predetermined positions.

4. A tissue drill as claimed in claim 3 wherein said predetermined positions are programmable.

5. A tissue drill as claimed in claim 3 wherein said handpiece is adapted to receive said optical fiber in controlled, rotatable relationship thereto.

6. A tissue drill as claimed in claim 5 wherein said laser outlet end of said optical fiber is rotatable while reciprocating between said predetermined positions.

7. A tissue drill as claimed in claim 6 wherein said laser outlet end is eccentric.

8. A tissue drill as claimed in claim 3 wherein said predetermined positions include a position in which said laser outlet end is proximal to said distal end.

9. A tissue drill as claimed in claim 1 wherein said tissue drill is adapted to ablate heart tissue.

10. A tissue drill as claimed in claim 9 wherein said heart tissue is myocardium.

11. A handpiece for use in a laser tissue drill for reduced-trauma tissue ablation, said handpiece comprising:

a body portion having a distal end; and

a coupling portion for receiving an optical fiber in controlled, axially movable relationship with respect to said body portion.

12. A handpiece as claimed in claim 11 wherein said coupling portion includes a drive for moving an outlet of the optical fiber to a position beyond said distal end.

13. A handpiece as claimed in claim 12 wherein said drive moves the outlet of the optical fiber to a position substantially at or near said distal end.

14. A handpiece as claimed in claim 12 wherein said drive reciprocates the outlet of the optical fiber between said positions.

15. A handpiece as claimed in claim 12 wherein said coupling portion is programmable for varying said position.

16. A handpiece as claimed in claim 11 wherein said coupling portion is adapted to receive the optical fiber in controlled, rotatable relationship.

17. A handpiece as claimed in claim 16 wherein said coupling portion includes a drive for moving an outlet of the optical fiber to an advanced position beyond said distal end;

said coupling portion being adapted to rotate the outlet while moving the outlet to said advanced position.

18. A handpiece as claimed in claim 17 wherein said drive moves the outlet of the optical fiber to a retracted position substantially at or near said distal end;

said coupling portion being adapted to rotate the outlet while moving the outlet from said advanced position to said retracted position.

19. A handpiece as claimed in claim 18 wherein said drive is adapted for reciprocating the outlet of the optical fiber between said advanced position and said retracted position.

20. A handpiece as claimed in claim 17 wherein said coupling portion is programmable for varying said advanced position.

21. A handpiece as claimed in claim 11 wherein said body portion is a catheter.

22. An optical fiber for use in a laser tissue drill for reduced-trauma tissue ablation, said optical fiber comprising:

an elongate portion having a core with an inlet for receiving laser energy, said core having an axis;

an outlet portion having a core with an outlet for emitting laser energy, said core having an axis at said outlet eccentric to the axis of said core of said elongate portion.

23. An optical fiber as claimed in claim 22 wherein said outlet portion has a diameter ranging from about 0.3 millimeter (mm) to about 1 mm.

24. An optical fiber as claimed in claim 22 wherein said outlet portion has a length of approximately 50 mm.

25. An optical fiber as claimed in claim 22 wherein said elongate portion has a length of approximately 2 meters.

26. An optical fiber as claimed in claim 22 wherein said outlet portion includes an auxiliary cladding with an axis substantially concentric with the axis of said core of said elongate portion.

27. An optical fiber as claimed in claim 22 wherein said outlet portion has an end surface from which said outlet emits laser energy;

said outlet having a diameter of at least approximately one half of a diameter of said end surface.

28. An optical fiber as claimed in claim 27 wherein the diameter of said end surface is approximately 1 mm and the diameter of said outlet is approximately 0.6 mm.

29. A method for performing reduced-trauma tissue ablation, said method comprising the steps of:

providing a laser energy source for generating laser energy;

providing a tissue drill including a handpiece with a distal end and an optical fiber with an inlet for receiving laser energy from said laser energy source and an outlet for emitting laser energy, said handpiece receiving said optical fiber in a movable relationship so that said outlet is advanceable beyond said distal end;

positioning said distal end of said handpiece near or against tissue to be ablated; and

advancing said optical fiber into the tissue while emitting laser energy from said outlet.

30. A method as claimed in claim 29 further comprising the step of:

retracting said optical fiber from the tissue.

31. A method as claimed in claim 30 wherein said retracting step comprises the step of retracting said optical fiber while terminating emission of laser energy from said outlet.

32. A method as claimed in claim 29 wherein said advancing step comprises the step of advancing said optical fiber into the tissue while rotating said outlet.

33. A method as claimed in claim 32 wherein said providing step comprises the step of providing said tissue drill with said optical fiber with said outlet, said outlet having an axis eccentric to an axis of rotation of said optical fiber.

34. A method as claimed in claim 29 wherein said advancing step comprises the step of advancing said optical fiber into the tissue at a varying rate of speed.

35. A method as claimed in claim 29 wherein said advancing step comprises the step of advancing said optical fiber into the tissue while emitting laser energy at varying levels.

36. A method as claimed in claim 29 wherein:

said step of providing a tissue drill comprises the step of providing a tissue drill including a handpiece configured as a catheter; and

said positioning step comprises the step of positioning said distal end of said handpiece endovascularly.

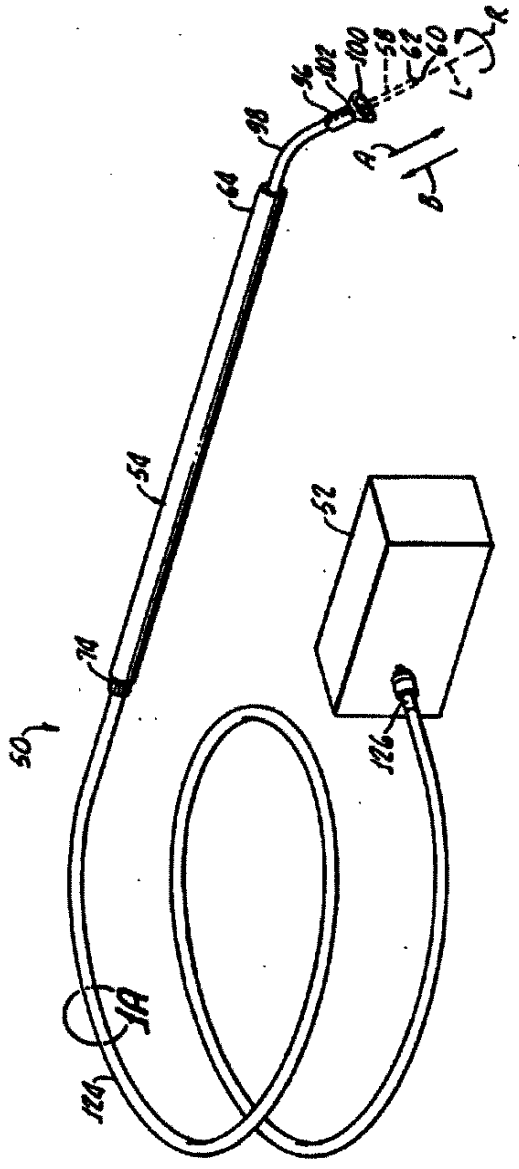

FIG. 1

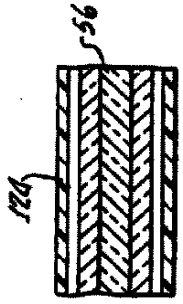

FIG. 1A.

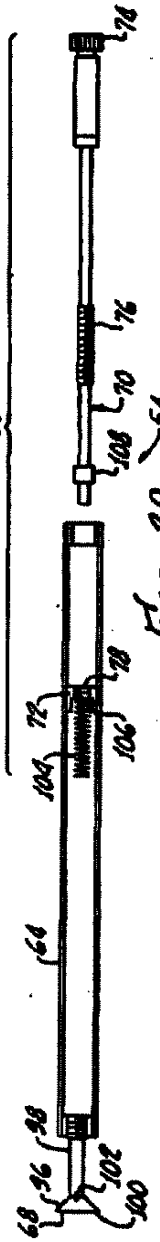

FIG. 3A.

FIG. 3B.

FIG. 2A.

FIG. 2B.

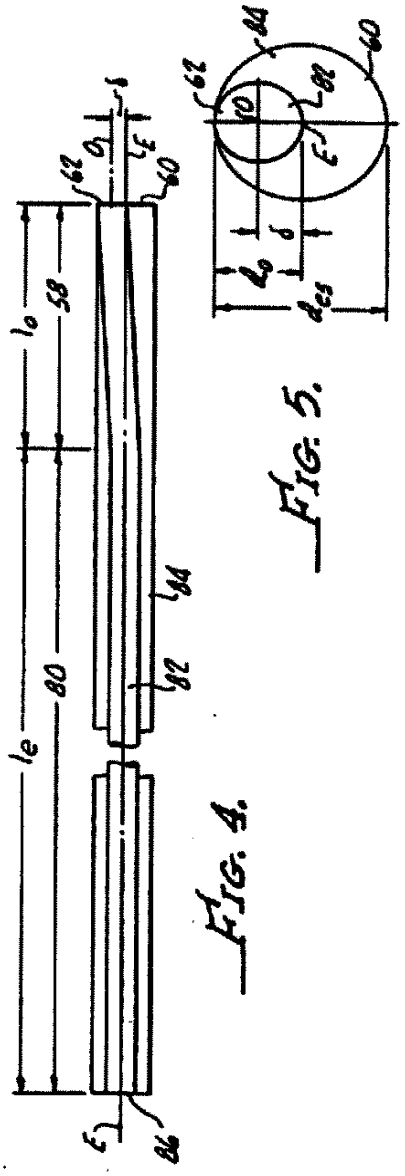

FIG. 4.

FIG. 5.

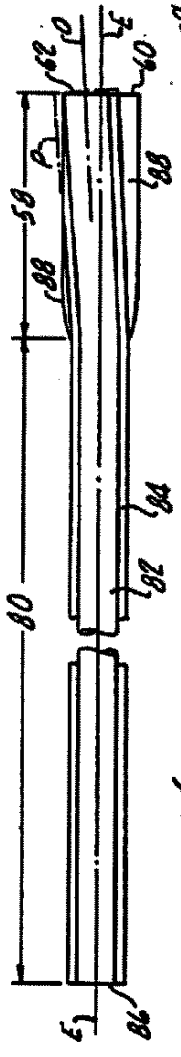

FIG. 6.

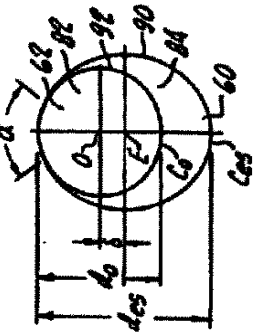

FIG. 7.

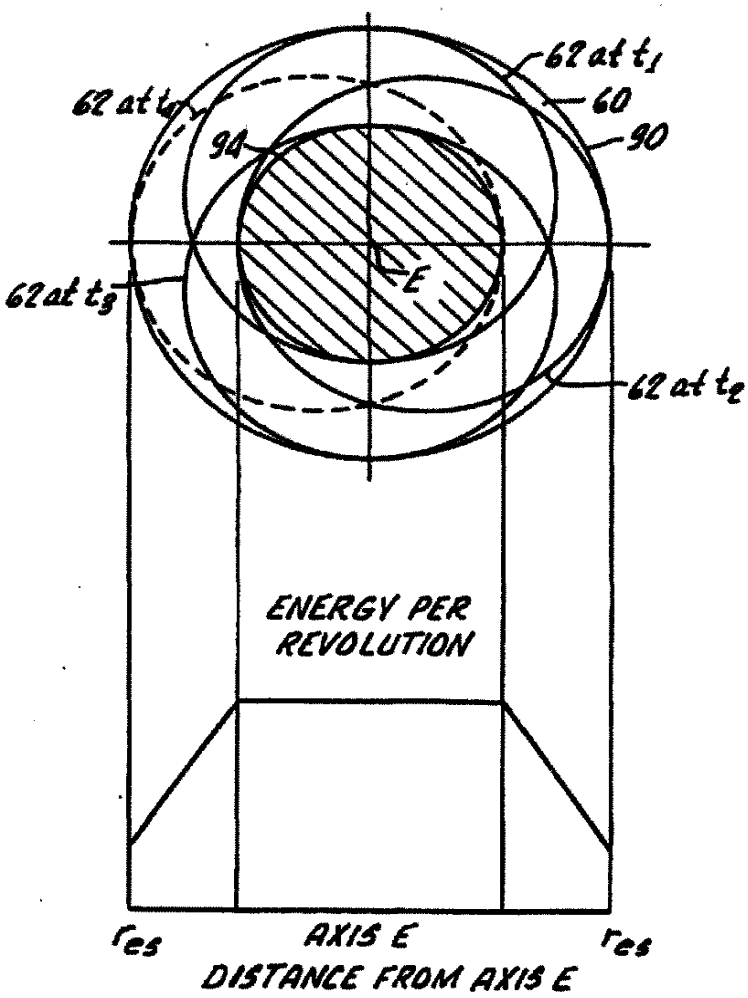
62 at t_1
62 at t_4
60
94
90
E
62 at t_3
62 at t_2
ENERGY PER REVOLUTION
r_{es}
AXIS E
r_{es}
DISTANCE FROM AXIS E

FIG. 8.

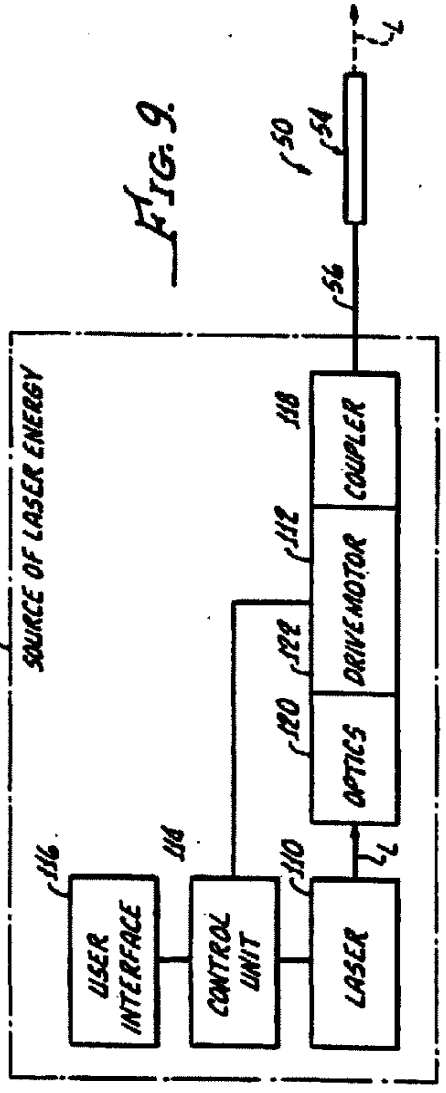

FIG. 9.

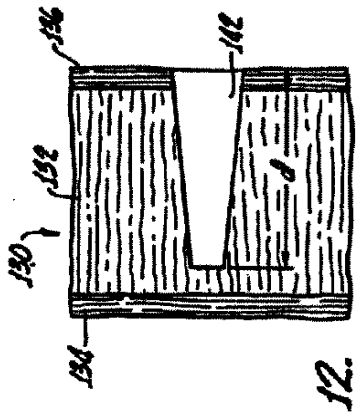

FIG. 12.

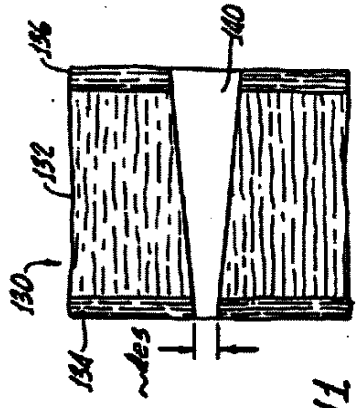

FIG. 11.

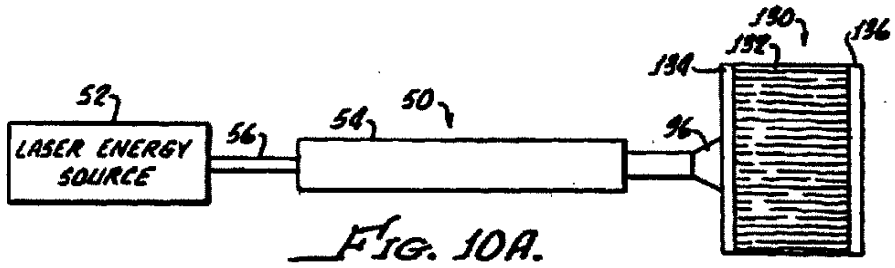

FIG. 10A.

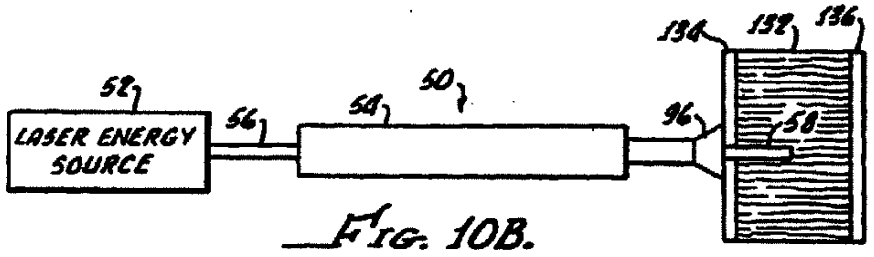

FIG. 10B.

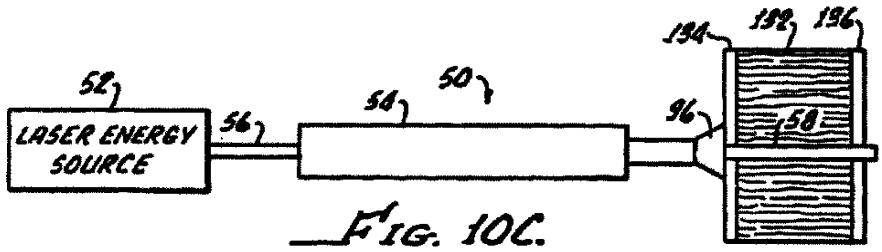

FIG. 10C.

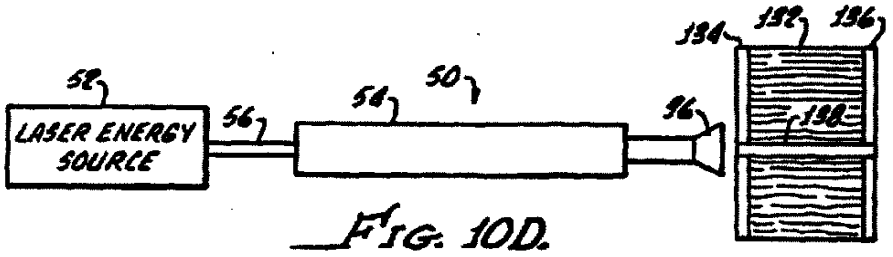

FIG. 10D.

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 98/20648

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G02B6/02 A61B17/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B G02B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 266 548 A (DAVI S K) 12 May 1981 see column 10, line 1 - column 11, line 68; figures 14-16	1-21
X	US 5 562 658 A (LONG GARY) 8 October 1996 see column 5, line 51 - column 6, line 26	1-4, 8-15, 22-28
X	EP 0 797 957 A (ECLIPSE SURGICAL TECH) 1 October 1997 see column 13, line 29 - line 55; figures 7,8	1-4, 8-15,19
X	CA 2 201 670 A (ECLIPSE SURGICAL TECH) 5 October 1997 see figure 3	1-4, 8-15,19

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 January 1999	08/02/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gérard, B

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/20648

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 988 163 A (COHEN MARTIN G ET AL) 29 January 1991 see column 4, line 11 - line 32	22

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No:
PCT/US 98/ 20648

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-21

   LASER DRILL FOR TISSUE ABLATION

2. Claims: 22 - 28

   OPTICAL FIBRE WITH OFFSET OUTLET PORTION

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inta. onal Application No
PCT/US 98/20648

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4266548 A	12-05-1981	EP 0020749 A	07-01-1981
		WO 8001238 A	26-06-1980
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EP 0797957 A	01-10-1997	US 5725521 A	10-03-1998
		AU 1660097 A	02-10-1997
		CA 2200916 A	29-09-1997
		JP 10033550 A	10-02-1998
CA 2201670 A	05-10-1997	US 5782823 A	21-07-1998
		AU 1668797 A	09-10-1997
		EP 0799604 A	08-10-1997
		JP 10024047 A	27-01-1998
US 4988163 A	29-01-1991	NONE	